

Applicant : James P. Koch  
Serial No. : 09/400,817  
Filed : September 22, 1999  
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Attorney : Docker No.: 01996-005001

## REMARKS

### *Status of Claims*

Claims 1-3, 5-6, 8-17, 19-36, 39-48 and 50-59 are in the case. Claims 1, 17, 23 and 33 have been amended herein. Claims 2-3, 5-6, 8-16, 19-22, 24-32, 34-36, 39-51 remain unchanged. Claims 52-59 have been added. Claim 57 contains the features recited in claims 33 and 49, which the Examiner indicated would be allowable if placed in independent form.

### *Rejections Under 35 U.S.C. §102(b)*

The Examiner has rejected claims 1-3, 5-6, 10-11 and 44-46 as being anticipated by Lipfert; claims 17, 19-20 and 23-27 as being anticipated by Shields; and claims 33-36, 39-40 and 51 as being anticipated by Goepp (U.S. 4,363,318). Applicant will discuss these rejections in turn, as they pertain to the independent claims.

#### *Lipfert (Claim 1)*

Claim 1, as amended, requires that the cap dome be custom-molded to substantially completely conform to the shape of the patient's cervix. Because the cap dome conforms closely to the shape of the patient's cervix, bacterial growth within the cap is inhibited, allowing the cap to be safely left in place for long periods of time. Because it is not necessary to insert the cap before intercourse and remove it a predetermined time after intercourse, the cap may be used easily and conveniently, reducing the chance of unwanted pregnancy due to failure to use the cap or improper placement of the cap.

The cervical cap described by Lipfert does not include a custom-molded cap dome. Instead, the cap dome (cup-shaped body portion 22) of the Lipfert cervical cap is pre-formed.

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***Shields (Claims 17 and 23)***

Like Lipfert, Shields does not teach a cervical cap having a custom-molded cap dome. Instead, Shields describes a conventional, pre-formed vaginal diaphragm.

***Goepp (Claims 33, 34 and 51)***

Claims 33, 34 recite a kit, and claim 51 recites a method, for custom-forming a cervical cap by applying to the cervix a rim member, i.e., a member that does not cover the patient's exocervix, to which a curable material is bonded. When the finished cap is in use, the rim member provides an exceptionally secure seal between the rim of the cap and the patient's exocervix. The curable material may be applied to the rim member and exocervix without first applying a shell member (as recited in claim 51). Alternatively, a shell member (provided in the kit recited in claim 34) is first applied to the rim member to define a cavity to receive the curable material. In this case, the shell member is removed once the curable material has hardened. The use of a separate rim member allows the rim to be snugly fitted to a patient's exocervix, by allowing a clinician to easily keep in stock a wide range of different diameter rims.

Goepp does not teach or suggest a separate rim member to which curable material is applied and bonded. Instead, Goepp teaches a cap having a cap dome that terminates in a peripheral edge 35. (See, e.g., Figs. 1 and 2 and col. 5, line 61 - col. 6, line 6.)

For at least the reasons discussed above, Applicant's claims are not anticipated by the cited references. Applicant respectfully requests that the rejections under §102 be withdrawn.

***Rejection Under 35 U.S.C. §103(a)***

The Examiner has rejected claims 8-9, 12-17, 19, 21-27, 41-43 and 47-48 as being unpatentable over Lipfert in view of Shields.

These claims are patentable for the reasons discussed above. Each of the above claims requires that the cervical cap include a custom-molded cap dome. As discussed, neither Lipfert nor Shields teaches or suggests a cervical cap having a custom-molded cap dome.

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*New Claims 58 and 59*

Claims 58 and 59 require, respectively, a snugly fitting rim member to which a cap dome is bonded, and that the rim member have one or more ridges configured to allow the rim member to securely grip the exocervix. As discussed above, none of the cited references teach or suggest a cervical cap that includes a rim member and a custom molded cap dome that is bonded to the rim member. Nor do any of the references teach or suggest such a rim member having ridges to allow it to grip the patient's exocervix. As a result, Applicant submits that claims 58 and 59 are patentable over the art of record.

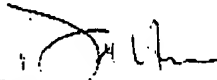
*Conclusion*

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a \$225.00 check for excess claim fees and a \$55.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 12/21/01

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Version with markings to show changes made

In the claims:

Claims 1, 17, 23 and 33 have been amended as follows:

-- 1. (Three times amended) A cervical cap comprising:  
a rim member dimensioned to fit a patient's exocervix;  
a cap dome extending from the rim member to cover the exocervix and having an opening to allow fluid flow out of the cap dome, the cap dome being custom-molded to substantially completely conform to the shape of the patient's cervix; and  
a valve associated with the opening, constructed to allow outflow while preventing fluid flow into said cap dome.

17. (Three Times Amended) A cervical cap comprising (a) a [custom molded] cap body[,] that is constructed to cover the exocervix and prevent ingress of sperm and fluids and includes a cap dome that is custom-molded to substantially completely conform to the shape of the patient's cervix, and (b) a portion, associated with the cap body, that is impregnated or coated with a therapeutic agent and is constructed to release the therapeutic agent over a period of time during use of the cap.

23. (Three Times Amended) A method of protecting the exocervix of a female, comprising applying to the exocervix a custom molded cervical cap [that includes] comprising (a) a cap body that includes a cap dome that is custom-molded to substantially completely conform to the shape of the patient's cervix, and is constructed to cover the exocervix and prevent ingress of sperm and fluids, and (b) a portion that is impregnated or coated with a therapeutic agent, the portion being constructed to slowly release the therapeutic agent during use of the cap.

33. (Three Times Amended) A kit for use by a clinician in forming a custom cervical cap in situ, in a patient's body, comprising in combination a rim member dimensioned to fit an

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exocervix, the rim member including a substantially ring-shaped surface that, when the rim member is placed on the exocervix, faces toward the opening of the patient's vagina, a curable material, and a means for applying the curable material to the ring-shaped surface.--